

MAR 12 2007

# DRAFT

## In the Specification

Please replace the title of the application with the following:

### **Therapeutic Dental Devices**

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Please insert the following paragraph as the last paragraph under the heading, "BRIEF DESCRIPTION OF THE DRAWINGS", on page 6:

FIGs. 9 and 10 depict partial cross-sectional views of embodiments of delivery devices of the present invention.

FIG. 11 depicts a roller ball applicator.

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Please replace paragraphs [0051], [0053], and [0055] with the following amended paragraphs:

[0051] The inventive compositions are preferably disposed in a delivery device 10 (e.g., FIGS. 2-4), such as a dispensing tube, pencil, pen or liquid stick having an applicator 12, such as a felt tip 14 (FIG. 3), brush 16 (FIG. 4), roller ball 17 (FIG. 11), or non-woven pad. In one embodiment, the delivery device 10 includes more than one applicator 12 that may be removably engaged with the device 10. In an embodiment wherein the device 10 is a pen or a pencil, the applicator 12 may be retractable and/or housed in a cap 18. The therapeutic dental composition L of the present invention may be housed directly within a reservoir 20 in the device 10 or may be supplied in a removable cartridge (not shown) within the reservoir 20 that may be replaced or refilled. The delivery device 10 may dispense the

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therapeutic dental composition through a transfer channel 21 through capillary action, such as in a flow through pen, or through an activator 22, such as mechanical piston 23 with a click mechanism 25, as shown in FIG. 9, twist button and ratchet mechanism 27, as shown in FIG. 10, or push button mechanism, or through a vacuum method of ejection, or through other such mechanical means for transferring the composition from the device to an oral cavity surface in need of treatment. The activator 22 may be present on first end 24 of the device 10 and the applicator on a second end 26 of the device 10 or the activator 22 may be present on a side wall 28 of the device. In one embodiment, the delivery device 10 includes a felt tip 14 or brush 16 applicator 12 wherein the inventive composition is dispensed to the applicator 12 through actuation of the activator 22, such as by a clicking 25 or twisting mechanism 27. Kotobukie Company Pencil, Japan, is one manufacturer of such types of delivery devices 10. [0053] Upon applying external pressure to the activator 22 to expel the composition from the reservoir 20, the dental composition responds to shear forces introduced by the external pressure, and is temporarily reduced in viscosity to allow for ease of movement of the composition from the reservoir 20 through the transfer channel 21 to the applicator 12. Once the composition is positioned on the applicator 12, the user applies the composition to the teeth or gum surfaces, using the applicator 12 to apply and distribute the composition on the teeth and/or gums. Optionally, a set of instructions may be provided to the user in order that a particular application method or protocol be employed to apply the composition from the device 10 onto the teeth and/or gums in order to optimize the performance of the composition. With a twist mechanism 27, the user twists the activator 22 on the first end 24 of the delivery device 10 and the therapeutic dental composition L travels from the reservoir 20 through the transfer channel 21 to the applicator 12 at the other end. With the push button

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activator 22, the therapeutic dental composition L is delivered to the oral cavity surface with the push of a button activator 22 on the first end 24 or side wall 28, which transfers the composition from the reservoir 20 through the transfer channel 21 to the applicator 12.

[0055] The dental gel composition can be dispensed from any suitable delivery device 10 as described above. For example, the dental composition may be dispensed as a liquid or thin gel from a push button (FIG. 9) or twist actuated (FIG. 10) pen with an advancing piston mechanism 23 that expels a predetermined amount of liquid or gel through an orifice. The pen delivery device 10 just described may also optionally comprise a set of bristles, advantageously positioned near or around the orifice through which the therapeutic dental liquid or gel is expelled. Expelling the therapeutic liquid or gel through the orifice and onto said bristles, the user may apply the therapeutic composition directly onto the teeth, thereby forming a thickened gel upon application. Alternatively, the dental composition may be brushed onto an oral cavity surface, using a brush (FIG. 4) or felt tip (FIG. 3) that is replenished with the therapeutic composition by returning it to a reservoir containing said composition or by clicking or twisting a dispensing portion of the reservoir. Yet another mode of application is placement of the inventive therapeutic liquid or gel composition into a dental tray, whereupon the dental tray is inserted into place around a patient's teeth. Plastic strips may also be coated with a predetermined dose of the therapeutic responsive dental gel and placed against the teeth or gums of a subject. Alternatively, the inventive compositions may be applied by placing an amount on a swab or other such device, and simply applying directly to the intended oral cavity surface.